

Medical Products

TD

Safety Information

System

General Safety Notes

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Document revision level

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Important Remarks:

introduction

The following general safety notes are supplemented by specific descriptions in the documents supplied by us, e.g. product documents, ARTD (general guidelines) as well as by written instructions in specific cases.

All safety instructions must be observed in the performance of work and tests; in addition, there must be compliance with prescribed country-specific requirements (e.g. occupational safety and accident prevention regulations).

NOTE

- **The currently valid ARTDs are stored on the CS home page in the CS intranet.**
- **Select the following on the CS intranet home page -> “CS Guidelines“.**
- **The ARTDs are located under “CS Guidelines for Regional Units“.**

Change to the systems delivered by us

Changes made in products/systems shipped by us must not be implemented without our written release; this applies in particular to changes which may affect the mechanical and/or electrical safety or radiation-protection properties of a product (e.g. changing of safety distances, removal of locks/instructions, enlargement of the radiation exit window on the lead cone, etc.).



Warnings and pictorials

The use of signal words and the degree or level of hazard seriousness is based on the ANSI standard Z535.4



Danger

Text accentuation and its meaning in the technical documentation.



Tab. 1 GEFAHR / DANGER

 GEFAHR	Bei einer unmittelbar drohenden Gefahr, die bei Nichtvermeidung zum Tod oder zu einer schweren Körperverletzung führt .
 DANGER	Indicates when there is an immediate danger that leads to death or serious physical injury.

Tab. 2 WARNUNG / WARNING

 WARNUNG	Bei einer Gefahr, die bei Nichtvermeidung zum Tod oder zu einer schweren Körperverletzung führen kann .
 WARNING	Indicates a risk of danger that may lead to death or serious physical injury.

Tab. 3 VORSICHT / CAUTION

 VORSICHT	Bei einer Gefahr, die bei Nichtvermeidung zu einer leichten oder mittleren Körperverletzung und/ oder zu einer Sachbeschädigung führt oder führen kann.
 CAUTION	Indicates a risk of danger that leads to slight or moderate physical injury and/or damage to property.









Tab. 4 ACHTUNG / NOTICE

ACHTUNG	Bei einer Gefahr, die bei Nichtvermeidung zu einem unerwünschten Ergebnis oder Zustand führt oder führen kann (nicht Tod, Körperverletzung oder Sachbeschädigung).
NOTICE	Indicates a risk of danger that if disregarded leads or may lead to a potential situation which may result in an undesirable result or state (not death, physical injury or property damage).

Tab. 5 HINWEIS / NOTE

HINWEIS	Ist als Tipp zu verstehen. Der Anwender muss diese Anweisung nicht unbedingt beachten. Er erfährt jedoch Vorteile, wenn er dies tut.
NOTE	Should be understood as a tip. The user does not absolutely have to observe these instructions. However, there will be advantages if he does.





















Tab. 6 Display in hardcopy documentation and online

Paper (black/ white)	Online = html file (in color)
 DANGER	 (white type on red background)
 WARNING	 (black type on orange background)
 CAUTION	 (black type on yellow background)
NOTICE	 (black type on blue background)
NOTE	 (black type on green background)

Pictorials

The symbols appear in black/white in paper documents and in color online.

Tab. 7 Display in hardcopy documentation and online

Name	Paper	Online	Name	Paper	Online
Change in PGs			Protocol		
Training			Torque		
ESD			Caution		
Magnetic Field			X-ray		
Voltage			Laser		

Notes in technical documentation that are labeled with the following symbols have the meanings explained below:



For X-radiation

X-ray

Warning for ionizing radiation;
radioactive material ([Radiation protection / p. 10](#)).



With respect to caution

Caution

In older documentation, this symbol was also used as a note for a torque value.
Warning for a general dangerous situation.



With respect to torques

Torque

Note about a threaded connector with a torque value ([Screw connections / p. 11](#)).



With respect to measurement results to be entered

Certificate

Note for entry in certificates.



For lasers

Laser

Warning for a laser beam ([Laser beam / p. 11](#)).



For voltages

Voltage

Dangerous electrical voltage > 25 V~ or > 60 V- ([Work in connection with voltage / p. 10](#)).



For the magnetic field

Magnetic Field

Warning for a magnetic field



For electrostatically sensitive devices

ESD

Warning regarding electrostatically sensitive devices ([Protection for electrostatically sensitive devices / p. 11](#))

**Training**

- Mechanical or electrical work the execution of which is not described in the document. This type of work may be performed only by personnel who have the necessary training and a valid manufacturer's approval.
- Additionally required installation material has to be obtained on site. This material and all necessary procedures have to comply with the regulations pertaining to the installation site.
- This type of work may be performed only by personnel who have the necessary training and a valid manufacturer's approval.

**Only in Planning Guides**

Note regarding changes in Planning Guides

Please note:

Room installation

In the Federal Republic of Germany, the electrical installation in rooms used for medical purposes has to correspond to DIN VDE 0100-710 (IEC 60364-7-710).

For all other countries, the regulations to be complied with (national and VDE regulations) must be taken from the installation sheets for the project concerned.

Protective conductor connections

All work must be carried out in accordance with the technical documentation.

During installation or prior to start-up, ensure that all **protective conductor connections specified by the manufacturer** are properly established. This applies e.g., to all metal covers that in case of error could conduct hazardous voltages. These covers always have to be connected to the protective conductor. Establish the connection between the cover and protective conductor using a screw with a contact washer underneath, or using the specified protective conductor connectors.



; means **connection points for protective system conductors**

The protective ground wires must be connected between the system components and the power supply as shown in the wiring diagram.

To protect employees and third parties, protective conductor tests are to be performed prior to initially switching on the device/system, as well as after the conclusion of all work and prior to hand over to the customer, in accordance with the instructions in the technical documentation.

Personal safety measures (occupational health and safety)

The legally relevant and internal regulations and specifications concerning occupational safety and accident prevention must be observed, primarily in the interest of the persons performing the work.

The notes below are given as additional information.

Unpacking

- When unpacking, look for shipping damage that could later have an adverse effect on function and safety.
- Use only proper tools to avoid the risk of accident and damage to the contents.
- Each crate is secured with metal strapping. There is **serious risk** of accident, particularly **for eyes**, when cutting the straps. The cut ends can lash back unexpectedly.
- Pull only nails out of the crate boards that have a cardboard or metal disk under the heads.

Pull nails out completely and dispose of them properly. Wear sturdy shoes.

- Always observe the directional markings on the crates during transport, storage and unpacking.

Transport protection

All parts painted **red** on the unit as well as on the assemblies are transport safety devices that may be removed only in accordance with the instructions in the technical documentation.

Replacement for damaged or lost installation accessories

Damaged or missing installation hardware (such as steel cables, washers, etc.) may be replaced only with original parts.

Work in connection with voltage

It is prohibited to perform work on parts with voltage levels of $> 25\text{ V} \sim$ or $> 60\text{ V}$ (also refer to DIN VDE 0100-710 (IEC 60364-7-710)).

Power has to be switched off to the system using the EMERGENCY OFF switch.

This does not apply to measurement and adjustment activities. Extreme caution is required when performing these activities. However, only tools and measurement devices suited to these activities may be used.

Measurement and adjustment points have to be accessible to personnel without the risk of danger. If this is not possible, the equipment has to be shut down.

If power has to be applied during a work procedure e.g., to perform system movements, use caution when dealing with moving and rotating parts. Upon concluding the work, immediately switch off power to the system.



Risk of injury!

When working in the hazardous areas around products, there is a significant risk of injury due to unexpected system movements.

⇒ **Press the service or EMERGENCY STOP switch.**

Bodily protection

If there is any risk of injury, body protectors must be used. It is essential to observe the notes given in the documentation.

Radiation protection

Ionizing radiation can lead to radiation injuries if handled incorrectly. When radiation is applied, the required protective measures must be complied with in any event.

Mandatory reporting

The supervisor in charge must be notified at once in the event of an accident or if there are any hazards which may cause an accident.

For this, please observe the corresponding instructions.

Screw connections

Torque values for screw connections

All existing screw connections must be tightened sufficiently firmly, but they may not be overstressed when tightening.

There must always be compliance with stated torque values!

If "Loctite" is to be used to secure screws, it will be specified in the text.



Establish the correct screw connections.

Screw connections that are established incorrectly can result in physical injury or property damage.

⇒ **All screws are to be secured in accordance with the information in the documentation.**

Replacement for damaged or lost screws

Damaged or missing screws may be replaced only with the same screw types that have the specified hardness rating.

Unless a different value is listed in the instructions, all Allen screws used must be hardness rated 8.8.

Protection for electrostatically sensitive devices

The used integrated circuits and PC boards, which are equipped with electronic modules, require especially careful handling because of their electrostatically very sensitive structures and their extremely high input impedances.

Use the prescribed means of protection.

Laser beam

Depending on their classification, laser beams may damage the eyes and the skin (class 1 to 4). Please follow instructions as stated:

Tab. 8 Laser classes according to EN 60825-1

Class	Basic concept	Comments
1	The radiation emitted by the laser device is harmless.	No additional protective equipment is required
1M	Eye-safe when used without optical instruments. However, may not be safe when optical instruments are used.	No additional protective equipment is required as long as optical instruments are not used.
2	Eye-safe through human aversion reaction and blinking effect.	No additional protective equipment is required
2M	The light that can penetrate the pupil of the eye corresponds to a class 2 laser. Depending on the presence of a divergent or widened laser beam, it may not be safe when optical instruments are used.	No additional safety equipment is required as long as optical instruments are not used.
3R	Exceeds the MPE values ¹ Radiation is maximum five times higher than the GZE values of class 1 (or class 2). The risk is slightly less than with class 3B.	Hazardous to the eyes Safety glasses are recommended
3B	old class 3 B without 3 R Looking into the laser is hazardous. Diffuse reflections are considered harmless.	Hazardous to the eyes. Safety glasses are mandatory.
4	old class 4 Diffuse reflections are hazardous to the eyes. Potential fire hazard and a skin hazard.	Personal safety equipment is required (safety glasses, shielding)

1. MZB-Werten (MZB: Maximal zulässige Bestrahlung; engl. MPE: Maximum permissible exposure)

NOTE
Note the detailed instructions in the technical documentation!

Batteries

For replacement of batteries, special preventive measures apply.

In the case of lithium batteries, there is as risk of explosion if they are incorrectly installed.

The notes concerning handling and disposal must be observed in each case.

Working with heavy loads

In addition to wearing the required protective clothing, e.g., safety shoes and gloves, ensure that heavy loads are lifted and carried properly to prevent physical injury (e.g., to the spine).

The relevant instructions must be complied with.

Heavy or awkward loads must be moved by mechanical means or by several persons.

Handling hazardous substances *)

Hazardous materials is the designation for substances which can ignite or explode or which are toxic, injurious to health, corrosive or irritating.

Their properties together with the hazards and protective measures connected with them are identified clearly by symbols and described by the instructions appertaining to the hazardous substances.

Before they are handled, these instructions must be read and the required protective measures must be complied with when performing work to avoid health risks.

In addition, there must be compliance with all relevant instructions in the documentation.

Section	Changes
introduction	Link with reference to the ARTDs in the intranet has been corrected.
(Danger / p. 5)	The figure has been replaced by 5 tables.
(Pictorials / p. 6)	The symbols (Training / p. 8) and (Only in Planning Guides / p. 8) have been inserted. Table: (Tab. 7 / p. 6) added:
(Laser beam / p. 11)	Reference to the ARTD has been deleted Adjusted to standard DIN EN60825-1 (safety of laser installations)
(Room installation / p. 9)	“VDE regulation 0107” replaced by ”DIN VDE 0100-710 (IEC 60364-7-710)”.
(Work in connection with voltage / p. 10)	“(also refer to DIN VDE 0107:1994-10)” replaced by ”DIN VDE 0100-710 (IEC 60364-7-710)”.